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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/268,437	03/12/99	DING	UOC/134A

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EXAMINER

GABEL, G

ART UNIT	PAPER NUMBER
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1641

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DATE MAILED: 07/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/268,437

Applicant(s)

Halsall et al.

Examiner

Gail ne R. Gabel

Group Art Unit

1641



☒ Responsive to communication(s) filed on Feb 29, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-10 is/are pending in the application

Of the above, claim(s) 6-9 is/are withdrawn from consideration

☐ Claim(s) is/are allowed.

☒ Claim(s) 1-5 and 10 is/are rejected.

☐ Claim(s) is/are objected to.

☒ Claims 1-10 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received:

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s).

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Amendment Entry

1. Applicants' amendment and response filed 2/29/00 in Paper No. 6 is acknowledged and has been entered. Claims 1-5 have been amended. Claim 10 has been added. Claims 1-5 and 10 are pending and under examination.

Priority

2. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application in the first sentence of the specification (37 CFR 1.78). Applicant claims priority to Provisional Application No. 60/078,162 but such application is not referenced in the first sentence of the specification. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-5, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 is vague and indefinite in reciting "a cell adapted to hold a sample" because it is unclear what is encompassed by the term "adapted" so as to render the cell capable of holding a sample. Note, adapted denotes modification of some sort applied into an element.

Claim 1 is vague and confusing in reciting "a substrate having a plurality of analyte binding areas, each of said analyte binding areas having a different specific analyte binding substrate" because it is unclear how the analyte binding substrate which is part of the binding area which is further part of a substrate is structurally differentiated so as to render these two elements distinct from each other. It is unclear as to what the structural cooperative relationship is between these two elements in the limitation. See also claims 2-4.

In claim 4, insert "s" at the end of the term "substrate" to correct typographic error.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-5 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In this case, the specification does not appear to provide any **literal support** for the recitation of "does not have means to mix a sample in said cell" in claim 1. Applicants point to

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page 5 which discloses “a quiescent solution” but fails to provide literal support for such recitation. Applicants also point to page 12 of the specification for support which discloses “Fickian diffusion as the only mode of mass transport” but also fails to provide literal support for such recitation. Furthermore, none of the originally filed claims recited the limitation in question. Recitation of claim limitation lacking literal support in the specification or originally filed claims constitutes new matter.

Further, the specification does not appear to provide any **literal support** for the recitation of “analyte binding areas comprise impervious sheets” in claim 10. Applicants admit of the lack of such literal support in the specification for such recitation. Applicants point to the specification (page 11, line 15) which discloses use of “polystyrene sheet” but fails to provide literal support for such a recitation. Furthermore, none of the originally filed claims recited the limitation in question. Recitation of claim limitation lacking literal support in the specification or originally filed claims constitutes new matter.

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

7. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Meyerhoff et al. (US 5,981,203) for reasons of record.

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8. Claim 10 is rejected under 35 U.S.C. 102(e) as being anticipated by Meyerhoff et al. (US 5,981,203) in Figure 11 and 15 which includes PVC insulating layers.

Response to Arguments

9. Applicant's arguments filed 2/29/00 have been fully considered but they are not persuasive.
10. Applicants argue that the rejection of claims 1-5 as being anticipated by Meyerhoff et al. should be withdrawn in light of the new limitations incorporated as amendments into the claims because, as amended, the device in the instant invention is rendered suitable and particularly designed for miniaturization whereas the device of Meyerhoff et al. is totally unsuitable for miniaturization. Applicants contend that the instant invention differs from Meyerhoff et al. because Meyerhoff uses a porous support and requires a stirrer for continual washing of enzymatic product so that the device requires large volumes of liquid, thereby rendering it unsuitable for miniaturization.

In response, Meyerhoff et al. substantially discloses the claimed invention as illustrated in column 11, lines 3-27 and Figure 11 and does not exclude an embodiment claimed by the instant invention. Specifically, Meyerhoff et al. does not require use of stirrers to practice his invention.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., elements to render the device suitable for miniaturization) are not clearly recited in the rejected claims so as

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to define over the prior art cited. Applicant's arguments are not commensurate in scope with the claimed invention. Although claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

11. Applicants further argue that the Meyerhoff et al. invention requires a liquid pervious support for the electrodes. Applicants' attention is directed to Figures 11 and 15 for such a teaching; i.e., the PVC insulating layer.

In conclusion, applicants' arguments also fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. Applicant's arguments further do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

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12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gail Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays from 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

G. Gabel 7/31/03

Gail Gabel
Patent Examiner
Group 1641

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